

REMARKS

As a result of the foregoing amendments, the specification has been amended to incorporate a brief description of Figure 6, new claims 21-23 have been added and the abstract has been corrected for punctuation and grammar errors. Entry of these amendments and reconsideration of pending claims 1-16 and 19-23 are respectfully requested.

No new matter has been entered as a result of this amendment. The addition of the brief description of Figure 6 is supported by the text of Figure 6, as originally filed, and by portions of the specification that describe Figure 6, including the passage found from line 28 to line 32 of page 30 of the substitute specification. New claims 21-23 are directly supported by the preferred embodiments described in the first full paragraph of page 3 of the substitute specification. The amendments to the abstract serve only to correct punctuation and/or grammar errors and do not introduce new matter.

The objections of the July 29, 2003 Office Action to the drawings and abstract have been overcome by the foregoing amendments. The drawings were objected to because the originally filed specification contained no brief description of Figure 6. A brief description of Figure 6 has now been incorporated into the specification. The abstract was objected to for a punctuation error. This punctuation error has been corrected.

Claims 1, 4, 7-16 and 19-20 stand rejected under 35 U.S.C. 102(e) as being anticipated by US 6,074,850 to Antelman et al (hereinafter "Antelman"). Reconsideration and withdrawal of this rejection are respectfully requested. At column 15, line 26-31, Antelman states,

"This plasmid [pASN286-56] consisted of the adenovirus type 5 inverted terminal repeat (ITR), packaging signals and E1a enhancer, followed by the human smooth muscle  $\alpha$ -actin promoter and 286-56 cassette, and then Ad 2 sequence 4021-10462(which contains the E1b/protein IX poly A signal) in a pBR322 background."

Based on this passage in Antelman, the Office Action states,

"Absent evidence to the contrary, this plasmid [pASN286-56] contains a hybrid promoter that comprising [sic] an enhancer and the human smooth muscle  $\alpha$ -actin promoter with no intervening sequences and therefore are less than 1 kb apart.

Therefore, the plasmid of Antelman et al. meets the limitations of the instant invention."

Essentially, the rejection rests on the argument that the plasmid of Antelman *inherently* meets the instant claims limitation that the enhancer and promoter be less than 1 kb apart.

However, the disclosure of Antelman fails to support this theory of inherency. Apart from the fact that the human smooth muscle  $\alpha$ -actin promoter "follows" the E1a enhancer, there is absolutely no information in Antelman about the relative positions of the enhancer and promoter in the plasmid pASN286-56. Antelman contains insufficient information on the synthesis of plasmid pASN286-56 to enable one of skill in the art to determine the sequence of the plasmid in general or the sequence or size of the space between the enhancer and the promoter. Although the rejection baldly asserts that the distance between the enhancer and the promoter must have been less than 1 kb, no such fact can be determined from the disclosure of Antelman.

Distances greater than 1 kb are consistent with the disclosure of Antelman. Antelman simply states that the promoter "follows" the enhancer. Since one of skill in this art knows that the spacial relationship between enhancers and promoters can vary widely, with enhancers being of greatly varied distances both upstream and downstream of promoters, one of skill in the art would not conclude from the Antelman disclosure that the enhancer and promoter of pASN286-56 are *inherently* within 1 kb of each other. Accordingly, this rejection should be withdrawn.

Applicants note that new claims 21-23 further limit the distance between the enhancer and promoter and that these claims likewise should not be rejected as anticipated over Antelman.

Claims 1-16 and 19-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Antelman in view of Boshart, et al. Cell (1985) 41:521-530 (hereinafter "Boshart"). Reconsideration and withdrawal of this rejection are respectfully requested. This rejection cites Boshart strictly for the disclosure of an alternate enhancer to the E1a enhancer taught by Antelman. Accordingly, the combination of Boshart and Antelman fails to anticipate or make obvious the instant invention,

because the combination provides no teaching or suggestion of the instant limitation that the enhancer and promoter must be within 1 kb of each other.

Applicants respectfully submit that the application is now in condition for allowance and request prompt notice thereof.

Respectfully submitted,



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